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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>14D2165210    | <b>(X3) Date Survey Completed</b><br>10/09/2019 |
| <b>Name of Provider or Supplier</b><br>Campbell Health Solutions   | <b>Street Address, City, State</b><br>16650 S Harlem Ave, Tinley Park, IL |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory records and interview with the laboratory director (LD); the laboratory failed to establish policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209 (Laboratory Personnel Report). 2. On survey date 10-09-2019, at 2:15 pm, the LD confirmed the laboratory failed to establish a competency assessment policy.</p> |
| <b>D5217</b>              | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for toxicology testing in 2019. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish a policy for the bi-annual assessment of toxicology analytes tested on the Indiko Plus chemistry analyzer. Analytes Cocaine Metabolites Opiates Methadone Metabolites Amphetamines</p>  |

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|                     | <p>Barbiturates Oxycodone 6-Acetylmorphine Benzodiazepines Buprenorphine Opiates (Hydrocodone) 2. Review of laboratory records revealed the laboratory failed to perform bi-annual method accuracy evaluations for toxicology analytes tested on the Indiko Plus chemistry analyzer. 3. Interview with the LD on 10-09-2019, at 2:15 pm, confirmed the laboratory failed to establish a policy and perform bi-annual method accuracy evaluations in 2019.</p>  |
| <p><b>D5401</b></p> | <p><b>PROCEDURE MANUAL</b><br/>CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have a procedure manual for all tests performed in the specialty of toxicology. Findings Include: 1. Review of laboratory's policy and procedure manual revealed the laboratory failed to have procedures in place for toxicology testing performed on the Indiko Plus analyzer for the following analytes: Analytes Cocaine Metabolites Opiates Methadone Metabolites Amphetamines Barbiturates Oxycodone 6-Acetylmorphine Benzodiazepines Buprenorphine Opiates (Hydrocodone) Creatinine (For Specimen Adulteration) 2. On survey date 10-9-2019, at 2:15 pm, the LD confirmed no toxicology procedures were available for review.</p>  |
| <p><b>D5413</b></p> | <p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b><br/>CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on direct observation, review of laboratory records, and interviews with testing personnel (TP) #1 and the laboratory director (LD); the laboratory failed to monitor the temperature and humidity of the laboratory to ensure accurate and reliable operation of the of the Indiko Plus toxicology analyzer and ensure proper specimen storage. Findings Include: 1. Direct observation of the laboratory facility on 10-09-2019 at 11:30 am identified the room where the Indiko Plus analyzer was operated and patient urine specimens were stored. No thermometer was observed in the room to monitor the temperature and humidity. 2. Review of preventative maintenance logs for 2019 found no documented recordings of room temperature and humidity where the Indiko Plus analyzer was located and urine specimens were stored. 3. Review of the Indiko Plus operations manual on page 2 of the chapter "Operating environment" revealed the following operating conditions: Ambient temperature 18...30 Celsius Relative humidity: 40 - 80%, non-condensing" 5. Interview with TP#1 on 10-09-2019,</p> |

at 11:55 am, confirmed room temperature and humidity were not monitored for the Indiko Plus analyzer. 6. Review of the manufacturer's product inserts for the toxicology analytes tested on the Indiko Plus analyzer revealed that urine specimens can be stored at room temperature for up to 7 days. 7. Interview with TP#1 on 10-09-2019, at 11:55 am, confirmed room temperature is not monitored for urine specimens. 8. On survey date 10-09-2019, at 2:15 pm the findings were confirmed by the LD.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory records, and interviews with testing personnel (TP) #1 and the laboratory director (LD); the laboratory failed to ensure reagents were labeled with expiration dates to ensure accurate and reliable testing on the Indiko Plus toxicology analyzer in 2019. Findings Include: 1. Direct observation of the laboratory facility on 10-09-2019 at 11:30 am identified calibration and control reagents stored in a Frigidaire refrigerator, serial number WA91003430. 2. Direct observation of calibration and quality control reagents on 10-09-19 at 11:30am revealed the laboratory failed to document the date each reagent vile was opened and when it would expire. 3. Review of the laboratory documents, "Campbell Health Solutions Indiko Plus Calibrator Information" and "Campbell Health Solutions Indiko Plus Control Positions" revealed expiration information for the calibrator and control reagents upon opening. The following reagent stabilities are listed below: Reagent Open Vial Stability Hydrocodone 300 60 Days after opening CEDIA Negative Urine Cal 60 Days after opening Heroin Metabolite Cutoff Cal 60 Days after opening Buprenorphine 0 Cal 60 Days after opening Buprenorphine 5 Cal 60 Days after opening Buprenorphine 20 Cal 60 Days after opening Buprenorphine 50 Cal 60 Days after opening Buprenorphine 75 Cal 60 Days after opening DOAT 2 30 Days after opening/expiration date DOAT 3 30 Days after opening/expiration date DOAT 4 30 Days after opening/expiration date DOAT 5 30 Days after opening/expiration date Hydrocodone Low 60 Days after opening/expiration date Hydrocodone High 60 Days after opening/expiration date 4. Review of laboratory records revealed the laboratory failed to indicate when 14 of 14 reagents listed above were opened for use and when they would expire. 5. Interview with TP#1 on 10-09-2019, at 11:55 am, confirmed the dates when control and calibration reagents were opened was not documented and the expiration dates for those reagents were unknown. 6. Review of test volume records from June of 2019 through September of 2019 found the laboratory performed 7,326 toxicology tests on the Indiko Plus analyzer. 7. On survey date 10-09-2019, at 2:15 pm, the findings were confirmed by the LD.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform and document weekly preventative maintenance for 4 of 4 months reviewed and monthly maintenance for 1 of 4 months reviewed on the Indiko Plus toxicology analyzer. Findings Include: 1. Review of the operator's manual for the Indiko Plus analyzer in section 22, "Maintenance", indicated weekly and monthly maintenance procedures that should be performed and documented. Weekly Perform End of Day Procedure Backup database on USB flash drive Exit Software and Power Dow Workstation and Instrument Wash liquid and solid waste reservoirs Wipe up condensed water from reagent storage (if necessary) Clean reagent /sample racks Clean and check probes and mixing paddle Clean the wash wells Power Up the Instrument and Workstation Monthly Perform End of day procedure Clean water containers and tubing Exit Software and Power Down Workstation and Instrument Clean incubator cuvette positions Power Up the Instrument and Workstation 2. Review of "Maintenance Checklist" logs for the Indiko Plus analyzer revealed weekly maintenance was performed only 1 time each month rather than each week for 4 of 4 months reviewed (June 2019 through September 2019). 3. Review of the "Maintenance Checklist" documentation found that monthly maintenance was not performed and documented for 1 of 4 months reviewed (June 2019 through September 2019). No monthly maintenance was documented in September of 2019. 4. On survey date 10-09-2019, at 2:15 pm, the surveyor's findings were confirmed by the LD.

**D5787**

**TEST RECORDS**  
 CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:  
 Based on review of laboratory records and interviews with testing personnel (TP)#1 and the laboratory director (LD); the laboratory failed to identify each person who performed urine drug screens on the Indiko Plus toxicology analyzer for 5 of 5 patient test reports reviewed in 2019. Findings Include: 1. Review of 5 of 5 patient test reports revealed the testing personnel who performed the testing was not able to be identified on the report. Patient Identification Test Date P1 06-14-2019 P2 07-26-2019 P3 09-03-2019 P4 08-19-2019 P5 09-30-2019 2. Interview with TP#1 on 10-09-2019, at 12:45 pm, confirmed the laboratory had no way to identify the person performing each patient test. 3. On survey date 10-09-2019, at 2:15 pm, the surveyor's findings were confirmed by the LD.

**D5805**

**TEST REPORT**  
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the laboratory's test reports failed to include interpretation information for urine toxicology testing performed on the Indiko Plus analyzer for 5 of 5 patient test reports reviewed. Findings Include: 1. Review of 5 of 5 patient test reports found the laboratory failed to indicate interpretation information for urine drug screen testing performed on the Indiko Plus analyzer. Patient Identification Test Date P1 06-14-2019 P2 07-26-2019 P3 09-03-2019 P4 08-19-2019 P5 09-30-2019 2. The manufacturer's instructions for the DRI Amphetamine, Benzodiazepine, Methadone, Oxycodone, Opiate, Cocaine, CEDIA Heroin, and CEDIA Buprenorphine state, "The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) and Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 3. Interview with the LD on 10-09-2019, at 2:15 pm, confirmed the laboratory's patient test reports failed to include interpretation information for drugs of abuse screening on the Indiko Plus analyzer.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD), the LD failed to ensure a quality assessment plan was established. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to establish a quality assessment plan. 2. On survey date 10-09-2019, at 2:15 pm, the LD confirmed no quality assessment plan had been established for the laboratory.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel

have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the LD failed to ensure testing personnel (TP) received the appropriate training for urine toxicology testing on the Indiko Plus analyzer. Findings Include: 1. Review of the laboratory personnel report (CMS-209) identified 2 new TP, TP#1 and TP#2. 2. Surveyor requested initial training documentation for the 2 new TP on survey date 10-09-2019, at 9:30 am. 3. Review of training documentation revealed the laboratory failed to have training documentation for 1 of 2 TP, TP#2. 4. On survey date 10-09-2019, at 2:15 pm, the LD confirmed no initial had been documented for TP#2.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview of the laboratory director (LD); the LD failed to specify, in writing the duties and responsibilities of each person engaged in all phases of testing including which examinations and procedures each individual is authorized to perform and whether supervision is required for 3 of 3 individuals listed on the CMS-209 (Laboratory Personnel Report). Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the LD failed to specify, in writing, the duties and responsibilities for each person engaged in testing (director, clinical consultant, technical consultant, and testing personnel), including which examinations and procedures each individual is authorized to perform and whether supervision is required for 3 of 3 individuals listed on the CMS-209. 2. On survey date 10-09-2019, at 2:15 pm, the surveyor's findings were confirmed by the LD.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have a technical consultant (TC) who meets the qualification requirements of 493.1411. Findings Include: 1. The laboratory failed to have education and training documentation needed to qualify the TC listed on the CMS-209 (Laboratory Personnel Report). See D6035.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the laboratory director (LD); the laboratory's technical consultant (TC) failed to meet the qualification requirements for the position. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified testing personnel (TP) #1 as the TC. 2. Review of personnel records for TP#1 found no education documents or documented experience in toxicology testing for TP#1. 3. On survey date 10-09-2019, at 2:15 pm, the LD confirmed the laboratory failed to have education or experience documentation for the TC.

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. 2 of 2 TP listed on the CMS-209 (Laboratory Personnel Report), failed to meet the qualification requirements for moderate complexity testing. See D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have education and training documentation for 2 of 2 testing personnel listed on the CMS-209 (Laboratory Personnel Report). Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified 2 testing personnel (TP), TP#1 and TP#2. 2. Review of personnel records for TP#1 and TP#2, found the laboratory failed to have education documentation for TP#1 and education and training documentation for TP#2. 3. On survey date 10-09-2019, at 2:15 pm, the surveyor's findings were confirmed by the LD.